

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )

ANGEL et al. )

US Serial No.: TO BE ASSIGNED )

For: WATER-SOLUBLE OR WATER-DISPERSIBLE (CO) POLYMERS OF  
HYDROXYALKYL (METH)ACRYLATES, A PROCESS FOR THEIR  
PREPARATION, AND THEIR USE AS COATING AGENT, BINDER AND/OR  
FILM-FORMING EXCIPIENT IN PHARMACEUTICAL DOSAGE FORMS

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the above-identified U.S. National  
Stage application, kindly amend the application as follows.

CLEAN VERSION OF ALL CLAIMS

1. A water-soluble or water-dispersible copolymer obtainable by free-radical polymerization of
- a) 80 to 20% by weight of hydroxy-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate and, where appropriate, one or more compounds of the formula (A) or (B)

with R<sup>1</sup> = H, C<sub>1</sub>-C<sub>6</sub>-alkyl,

R<sup>2</sup> = H, CH<sub>3</sub>,

R<sup>3</sup> = C<sub>1</sub>-C<sub>24</sub>-alkyl

or mixtures thereof

in the presence of

- b) 20 to 80% by weight of polyvinyl alcohol (PVA) and
- c) where appropriate 0 to 20% by weight of other polymerizable compounds (C).

2. A water-soluble or water-dispersible copolymer as claimed in claim 1, wherein the free-radical polymerization is an emulsion polymerization.

3. (amended) A water-soluble or water-dispersible copolymer as claimed in claim 1, wherein hydroxyethyl methacrylate is employed as hydroxy-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate.

4. (amended) A water-soluble or water-dispersible copolymer as claimed in claim 1, wherein the compounds of the formula (A)

are selected from the group of methyl methacrylate, methyl acrylate, methyl acrylate, or mixtures thereof.

5. (amended) A water-soluble or water-dispersible copolymer as claimed in claim 1, wherein the compounds of the formula (B) are selected from the group of C<sub>3</sub>-C<sub>24</sub>-vinyl esters.

6. (amended) A process for preparing water-soluble or water-dispersible copolymers as claimed in claim 1 by free-radical polymerization in an aqueous or nonaqueous but water-miscible solvent or in mixed nonaqueous/aqueous solvents.

7. A process as claimed in claim 6, wherein the polymerization takes place in the presence of from 30 to 55% by weight of polyvinyl alcohol.

8. (amended) A pharmaceutical dosage form comprising at least one water-soluble or water-dispersible copolymer as claimed in claim 1 as coating agent, binder and/or film-forming excipient.

9. (amended) The use of water-soluble or water-dispersible copolymers as claimed in claim 1 as coating agent, binder and/or film-forming excipient in pharmaceutical dosage forms.

MARKED-UP VERSION OF AMENDED CLAIMS

3. (amended) A water-soluble or water-dispersible copolymer as claimed in [either of claims 1 or 2] claim 1, wherein hydroxyethyl methacrylate is employed as hydroxy-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate.

4. (amended) A water-soluble or water-dispersible copolymer as claimed in [any of claims 1 to 3] claim 1, wherein the compounds of the formula (A) are selected from the group of methyl methacrylate, methyl acrylate, methyl acrylate, or mixtures thereof.

5. (amended) A water-soluble or water-dispersible copolymer as claimed in [any of claims 1 or 4] claim 1, wherein the compounds of the formula (B) are selected from the group of C<sub>3</sub>-C<sub>24</sub>-vinyl esters.

6. (amended) A process for preparing water-soluble or water-dispersible copolymers as claimed in [any of claims 1 to 5] claim 1 by free-radical polymerization in an aqueous or nonaqueous but water-miscible solvent or in mixed nonaqueous/aqueous solvents.

8. (amended) A pharmaceutical dosage form comprising at least one water-soluble or water-dispersible copolymer as claimed in [any of claims 1 to 5] claim 1 as coating agent, binder and/or film-forming excipient.

9. (amended) The use of water-soluble or water-dispersible copolymers as claimed in [any of claims 1 to 5] claim 1 as coating agent, binder and/or [film/forming] film-forming excipient in pharmaceutical dosage forms.

REMARKS

The claims have been amended to eliminate multiple dependency and to place them in better form for U.S. practice. Favorable action on the application is solicited.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in dark ink, appearing to read 'H B Keil', written in a cursive style.

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